**UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| MONIKA SWIECZKOWSKI and ARTUR SWIECZKOWSKI, | ) | |
| Plaintiffs, | ) | Case No. 24-cv-11016 |
| v. | ) | |
| BILLIONTOONE, INC., a Corporation, | ) | Judge Sharon Johnson Coleman |
| Defendant. | ) | |

**MEMORANDUM OPINION AND ORDER**

Plaintiffs Monika Swieczkowski and Artur Swieczkowski ("Plaintiffs") filed their First Amended Complaint against Defendant BillionToOne, Inc. ("Defendant") alleging violations of the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1, *et seq.*, ("ICFA") and common law claims of fraud and negligent misrepresentation. Before the Court is Defendant's Rule 12(b)(6) motion to dismiss. For the following reasons, the Court denies Defendant's motion to dismiss [28].

**BACKGROUND**

The following facts are accepted as true for the purpose of resolving Defendant's motion to dismiss.

Plaintiffs allege that Defendant markets and sells the UNITY Complete test, a non-invasive prenatal test ("NIPT"). Relevant here, the UNITY Complete test includes the "UNITY Aneuploidy Screen," which screens for chromosomal conditions such as Trisomy 18 (the "UNITY Complete Test"). Plaintiffs claim that on or prior to February 1, 2023, Defendant marketed the Unity Complete Test to physicians treating expecting parents, including Plaintiffs' physician Dr. Lipowich. Defendant's marketing materials included the following claims:

- UNITY Fetal Risk Screen leverages cell-free DNA to provide direct insights to the fetus, translating to ~3x increase in detection of affected pregnancies compared to traditional career screening.

- The first and only test that uses cell-free DNA to provide precise fetal insights for both recessive and chromosomal conditions.

- Know More. Know Early.

- UNITY Complete provides early detection of severe genetic conditions early in a pregnancy. Knowing early allows access to timely interventions and treatments.

- A single blood draw, as early as 10 weeks is all it takes to Know More and Know Early.

- Quantitative Counting Templates, proprietary to [Defendant], quantify fetal DNA molecules from cfDNA down to a single base pair. This makes it possible to determine the fetal genotype in maternal blood, providing an individualized risk for each pregnancy.

Plaintiffs allege that, contrary to these claims, the UNITY Complete Test cannot definitively diagnose chromosomal or genetic conditions, such as Trisomy 18, due to the potential for both false positives and false negatives. Defendant's brochure advertises that the UNITY Complete Test has both a 99.9% sensitivity rate (the test's ability to return a positive result if the patient has a disease) and specificity rate (the test's ability to correctly identify those who do not have the disease in question). However, Plaintiffs claim that the UNITY Complete Test's sensitivity rate for detecting Trisomy 18 is 96.15% to 98.83%.

Plaintiffs allege that Dr. Lipowich reviewed Defendant's marketing materials, which purportedly contained these claims. Based on these claims, on February 1, 2023, Dr. Lipowich recommended Plaintiffs undergo the UNITY Complete Test to determine their fetus's risk for chromosomal and genetic conditions, including Trisomy 18. Plaintiffs consented to using the UNITY Complete Test and Plaintiff Monika provided a blood sample for testing and analysis.

On February 9, 2023, Defendant transmitted Plaintiff Monika's UNITY Complete Test results to Dr. Lipowich's office. Defendant only provided Dr. Lipowich with the first page of the results: the "Summary of Results" page. The Summary of Results page of Plaintiff Monika's UNITY Complete

Test indicated that Plaintiff Monika was classified as "LOW RISK" for Trisomy 18 and that the fetus's risk of having Trisomy 18 was less than 1 in 10,000. Prior to testing, the Summary of Results page indicated that Plaintiff Monika's risk of having a child with Trisomy 18 was 1 in 411. Plaintiffs allege that the UNITY Complete Test results were misleading and false because the 1 in 10,000 risk calculation was not personalized and did not accurately reflect the true risk because it failed to account for the risk of a false negative. Plaintiffs allege that medical studies and scientific research purport to show that false negative rates for NIPT and Trisomy 18 can be as high as 7.9%. Furthermore, Plaintiffs allege that Defendant's own study revealed a false negative rate much higher than .0001. Plaintiffs further assert the 1 in 10,000 figure was similarly false and misleading as it gave the impression that the UNITY Complete Test was diagnostic, when, in fact, it was merely a screening tool.

Based on Defendant's claims and the UNITY Complete Test results, Plaintiffs declined further invasive testing. On August 7, 2023, Plaintiff Monika gave birth to Leo. Leo was transferred to the neonatal intensive care unit and was placed on a ventilator. A blood test revealed that Leo had Trisomy 18. Leo passed away three weeks later due to Trisomy 18. Plaintiffs allege that, absent the false and misleading representations in Defendant's marketing materials and the UNITY Complete Test results provided to them, they would have pursued further diagnostic testing, which would have revealed that Leo had Trisomy 18. Plaintiffs further assert that, upon receiving this diagnosis, they would have elected to terminate Plaintiff Monika's pregnancy.

On October 25, 2024, Plaintiffs filed this lawsuit. Plaintiffs filed the First Amended Complaint on February 21, 2025, alleging extraordinary pain, suffering, grief, sorrow, disfigurement, and emotional distress, in addition to medical bills. The First Amended Complaint also seeks punitive damages.

**LEGAL STANDARD**

A motion to dismiss pursuant to Rule 12(b)(6) for failure to state a claim tests the sufficiency of the complaint, not its merits. *See Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 736 (7th Cir. 2014). When considering dismissal of a complaint, the Court accepts well pleaded factual allegations as true and draws all reasonable inferences in favor of the plaintiff. *Erickson v. Pardus*, 551 U.S. 89, 94, 127 S. Ct. 2197, 167 L. Ed. 2d 1081 (2007) (per curiam); *Trujillo v. Rockledge Furniture LLC*, 926 F.3d 395, 397 (7th Cir. 2019). To survive a motion to dismiss, plaintiff must "state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). A complaint is facially plausible when the plaintiff alleges "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L.Ed.2d 868 (2009).

Rule 9(b) requires a party alleging fraud to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). This "ordinarily requires the 'who, what, when, where, and how' of the fraud, although the exact level of particularity that is required will necessarily differ based on the facts of the case." *AnchorBank, FSB v. Hofer,* 649 F.3d 610, 615 (7th Cir. 2011) (citation omitted).

**DISCUSSION**

**I. Learned Intermediary Doctrine**

To start, Defendant argues that Plaintiffs' claims are barred by the learned intermediary doctrine because the "limitations associated with NIPT screening tests, were well known in the medical community, as evidenced by the FDA warnings [Plaintiffs] themselves rely on." Dkt. 34, at 6.

The learned intermediary doctrine (the "Doctrine") imposes a duty on prescription drug and medical device manufacturers "to warn physicians of a drug's or a device's dangerous propensities." *Hansen v. Baxter Healthcare Corp.,* 309 Ill.App.3d 869, 881 (1999). Upon receiving such warning from a drug and/or medical device manufacturer, physicians, employing their medical judgment, have a duty

to relay such warnings to their patients. *Hansen,* 309 Ill.App.3d at 881. The Doctrine, however, confers no duty on a medical device or prescription drug manufacturer to warn physicians of the dangers of a medical device or drug that are known to the medical community. *Id.* at 881.

The Court is not convinced that the Doctrine applies to Plaintiffs' claims. First, Defendant fails to cite any caselaw where an Illinois court applied the Doctrine to an ICFA claim. While the cases cited by Defendant involve claims of fraud and negligence, the context in which courts applied the Doctrine to such claims were in products liability actions premised on a failure to warn theory. *See Ashman v., SK & F Lab Co., a subsidiary of SmithKline Beckman Corp.,* 702 F. Supp. 1401, 1404 (N.D. Ill. Dec. 23, 1988) (Hart, J.); *Fisher v. Ethicon, Inc.,* 2021 U.S. Dist. LEXIS 237231 (C.D. Ill. 2021) (McDade, J.) Defendant's proffered caselaw stands in stark contrast to this matter. For starters, this is not a products liability action. Even if the Doctrine could govern Plaintiffs' ICFA claim in addition to their state law causes of action, Defendant fails to show that Plaintiffs' claims are predicated on a failure to warn theory. Plaintiffs do not assert that Defendant's marketing materials and the UNITY Complete Test posed any undisclosed safety risk to individuals. Rather, Plaintiffs allege that such documents were misleading and deceptive because they did not properly disclose accurate and reliable information. The materials at issue in this case bear little resemblance to the drugs and medical devices involved in cases where courts have applied the Doctrine. Accordingly, the Court finds the Doctrine does not apply to Plaintiffs' claims.

## II. Count I: ICFA

To state a claim under ICFA, Plaintiff must allege four elements: (1) a deceptive act or practice; (2) an intent for the consumer to rely on the deception; (3) the occurrence of the deception during conduct involving trade or commerce; and (4) actual damage that was proximately caused by the deception. *See Davis v. G.N. Mortg. Corp.,* 396 F.3d 869, 883 (7th Cir. 2005).

Defendant puts forward two arguments in support of its motion: (1) because Plaintiffs did not actually see Defendant's marketing materials, the proximate cause element of ICFA is not satisfied; and (2) Plaintiff Monika's UNITY Complete Test results do not contain a misrepresentation and, therefore, do not satisfy the deceptive act or practice element of ICFA.

*1. Defendant's Marketing Materials*

"In order to establish the element of proximate causation, a plaintiff must prove that it was actually deceived by the misrepresentation. If the plaintiff has neither seen nor heard a deceptive statement, it cannot have relied on the statement and, consequently, cannot prove that the statement was the proximate cause of their injury." *Tri-Plex Tech. Servs., Ltd. v. Jon-Don, LLC,* 47 Ill. Dec. 694, 702 (Ill. 2024) (internal citations omitted). However, direct deception between the plaintiff and defendant is not required. *DeBouse v. Bayer,* 235 Ill.2d 544, 556 (2009). ICFA recognizes that "indirect deception" can satisfy the deceptive act element of ICFA provided that the plaintiff "indirectly" receives "communication or advertising from the defendant." *See DeBouse,* 235 Ill.2d at 556. "It is enough that the statements by the defendant be made with the intention that it reach the plaintiff and influence [plaintiff's] action, and that it does reach [plaintiff] and that [plaintiff] does rely upon it, to [plaintiff's] damage." *Id.* at 556 (internal citations omitted).

The Court finds Plaintiffs assert adequate facts to establish proximate causation to support their ICFA claim based on Defendant's marketing materials. In the First Amended Complaint, Plaintiffs allege that Defendant "made false and deceptive statements in its marketing and selling its product to Dr. Lipowich's office." Dkt. 22, at ¶ 77. Plaintiffs claim that "[o]n or prior to February 1, 2023, Dr. Lipowich reviewed Defendant's marketing materials and relied on the deceptive and/or misleading claims… in deciding to use and recommend Defendant's UNITY Complete test to patients, including [Plaintiffs], and he further relied on said deceptive and/or misleading claims when counseling [Plaintiffs] during their pregnancy." *Id.,* at ¶ 26. Importantly, Plaintiffs allege that the

statements in Defendant's marketing materials were seen by Dr. Lipowich, who, in turn, relied on these statements in ultimately deciding to recommend the UNITY Complete Test to Plaintiffs. *See contra De Bouse v. Bayer AG,* 235 Ill.2d 544, 560 (2009) (holding that indirect deception is not satisfied where plaintiff fails to allege that her particular doctor was deceived by defendant's advertisements); *see also contra Shannon v. Boise Cascade Corp.,* 208 Ill.2d 517 (2004) (finding no indirect deception where builder did not see statements). Accordingly, the Court finds Plaintiffs sufficiently allege facts to support their ICFA claim premised upon Defendant's marketing materials.

*2. UNITY Complete Test Results*

Deception under ICFA is circularly defined as "[a] statement [that] creates a likelihood of deception or has the capacity to deceive." *People ex. rel Hartigan v. Knecht Servs., Inc.,* 216 Ill.App.3d 843, 857, 575 N.E.2d. 1378, 1387, 159 Ill. Dec. 318 (Ill. App. 1991); *see also Bober v. Glaxo Wellcome Plc.,* 246 F.3d 934, 938 (7th Cir. 2001). A reasonable consumer standard is used to determine if deception has occurred. *Beardsall v. CVS Pharmacy, Inc.,* 953 F.3d 969, 972 (7th Cir. 2020). This standard requires a probability "that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." *Bell v. Publix Super Markets, Inc.,* 982 F.3d 468, 474-75 (7th Cir. 2020) (internal citations omitted). In determining whether a deceptive act occurred, courts must view the alleged false statements or omissions in the context of all the information available to the plaintiff. *Benson v. Fannie May Confections Brands, Inc.,* 944 F.3d 639, 646 (7th Cir. 2019).

Defendant contends that the UNITY Complete Test results do not contain a deceptive act or misrepresentation because it stated that Plaintiffs' fetus had less than a 1 in 10,000 chance of having Trisomy 18. While Defendant concedes the chance was small, the UNITY Complete Test results contained no representation that Plaintiffs' fetus had no risk of having Trisomy 18, so there was no deceptive act or misrepresentation. Plaintiffs claim that Defendant misrepresented the limitations of the UNITY Complete Test and falsely stated that the fetus's risk of having Trisomy 18 was 1 in 10,000.

Plaintiffs allege the 1 in 10,000 risk calculation itself is a misrepresentation because the purported risk was much higher as this risk calculation was not personalized to Plaintiff Monika and did not account for the risk of a false negative.

Here, the First Amended Complaint alleges that Plaintiffs only received the first page of the UNITY Complete Test results – the Summary of Results page. Dkt. 22, at ¶ 35. The Summary of Results page does not contain any disclaimer language that the UNITY Complete Test was subject to false negatives. *Id.* at ¶ 36. Plaintiffs contend that the false negative rates for NIPTs, like the UNITY Complete Test, and for Trisomy 18 "have been shown to be as high as 7.9%." *Id.* at ¶ 45. Plaintiffs also claim that Defendant's own study "revealed a false negative rate much higher than .0001." *Id.* at ¶ 16. The Summary of Results page also stated that the fetus's risk of having Trisomy 18 was 1 in 10,000 and classified the risk as "LOW RISK FETUS." *Id.* at Exhibit F. Plaintiffs assert that the 1 in 10,000 risk was not personalized to Plaintiff Monika because the calculation was generic and failed to account for the risk of false negatives. *Id.* at ¶ 43.

At the motion to dismiss stage, the Court must accept all well-pled allegations as true and construe the facts in the light most favorable to the plaintiff. *Lavalais v. Village of Melrose Park,* 734 F.3d 629, 632 (7th Cir. 2013). At this point in the litigation, the Court finds Plaintiffs have alleged sufficient facts to satisfy the misrepresentation element of their ICFA claim based on the UNITY Complete Test.

## III. Count II: Common Law Fraud

As Defendant's arguments for dismissal of Plaintiffs' common law fraud claim are intertwined with its arguments for dismissal of the ICFA claim, the Court denies Defendant's motion to dismiss Plaintiffs' common law fraud claim, for reasons discussed in Section II, *supra.*

## IV. Count III: Common Law Negligent Misrepresentation

Under Illinois law, to state a claim for negligent misrepresentation, a plaintiff must demonstrate "(1) a false statement of a material fact; (2) carelessness or negligence in ascertaining the truth of the statement by the party making it; (3) an intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statement; and (5) damage to the other party resulting from such reliance when the party making the statement is under a duty to communicate accurate information." *Capiccioni v., Brennan Naperville, Inc.,* 339 Ill.App.3d 927, 938 (Ill. 2003). Defendant contends that Plaintiffs' negligent misrepresentation claim fails for three reasons: (1) Defendant had no duty to communicate accurate information to satisfy the fifth element of the negligent misrepresentation inquiry; and (2) Plaintiffs did not reasonably rely on the UNITY Complete Test results to satisfy the fourth element of the negligent misrepresentation claim.

1. Duty to Communicate Accurate Information

The duty to communicate accurate information exists in two circumstances: (1) where defendant is in the business of supplying information to guide others business transactions; or (2) where the information results in physical injury to a person or causes damage to their property. *Brogan v. Mitchell Intern. Inc.,* 181 Ill.2d 178, 183 (1998).

*a. Defendant is in the Business of Supplying Information to Guide Others in Business Transactions*

Defendant contends that it supplies information to assist healthcare providers and patients in making critical decisions regarding pregnancy management, not for the purpose of guiding others' business transactions. Plaintiffs claim that Defendant, a healthcare company, is in the business of supplying information, in the form of UNITY Complete Test results, to physicians and their patients in order to guide business transactions, such as what tests and referrals physicians should make for their patients based on the results from the UNITY Complete Test.

In negligent misrepresentation cases, Illinois courts have focused on whether a defendant, in the course of their business or profession, supplied information for the guidance of others in their

business transactions with third parties. *Lang v. Consumers Ins. Service, Inc.,* 222 Ill.App.3d 226, 234-235 (Ill. 1991) (collecting cases). Plaintiffs assert that the healthcare decisions they made based on the UNITY Complete Test results "involve a series of business transactions between the patient and the provider of the hospital, including the decision whether to consent to various procedures in exchange for money." Dkt. 22, at ¶ 103. Defendant argues this allegation is "too great a stretch" to conclude that Defendant is in the business of supplying information to guide others' business transactions but fails to rebut Plaintiffs' allegations through any caselaw. "Perfunctory and undeveloped arguments, as well as arguments unsupported by pertinent authority, are waived." *White v. United States,* 8 F.4th 547, 552 (7th Cir. 2021).[1]

2. Justifiable Reliance on the UNITY Test results

When asserting a negligent misrepresentation claim, a plaintiff's reliance must be justified. *Capiccioni,* 339 Ill.App.3d at 939 (internal citations omitted). "A party is not justified in relying on representations when he or she had ample opportunity to ascertain the truth of the representations before acting." *Id.* If a plaintiff had ample opportunity to discover the truth, reliance is not justified. *Neptuno Treuhand-Und Verwaltungsgesellschaft Mbh v. Arbor,* 295 Ill.App.3d 567, 575 (Ill. 1998).

Defendant argues that Plaintiffs unjustifiably relied solely on the Summary of Results page of the UNITY Complete Test results. Because the Summary of Results page indicated the existence of two additional pages in the report and recommended Plaintiffs follow up with genetic counseling to discuss the implications of the report, Plaintiffs decision to rely only on the Summary of Results page was unreasonable. Plaintiffs allege that Defendant provided Dr. Lipowich with only the first page of Plaintiff Monika's UNITY Complete Test results. Dkt. 22, at ¶ 35. Plaintiffs also claim that Defendant

[1] As the Court finds that Defendant is in the business of supplying information for the guidance of others in their business transactions, and therefore satisfies the fifth element in the negligent misrepresentation analysis, the Court will not consider Defendant's argument that Plaintiffs were not physically injured as a result of the UNITY Complete Test result as such argument is inconsequential to the Court's ruling.

failed to provide Plaintiffs with access to an online portal that would allow them to access the entire report, which would have contained the disclaimer language on the risk false negatives. *Id.* at ¶ 37. However, such fact-intensive inquiry is not appropriate to resolve on a motion to dismiss. *See Forth v. Walgreen Co.,* No. 17-cr-2246, 2018 WL 1235015, at *6 (N.D. Ill. March 9, 2018) (Lee, J.); *see also Mfrs. Life Ins. Co. v. 1 Animation Networks, Inc.,* No. 04 C 8105, 2005 WL 1950666, at 2 (N.D. Ill. Aug. 10, 2005) (Lee, J.) ("The court cannot determine at the pleadings stage whether there was reasonable reliance in the absence of any evidence."). And the Court will not address the merits of the arguments at this time.

In sum, the Court denies Defendant's motion to dismiss Plaintiffs' negligent misrepresentation claim.

## V. Emotional Distress and Punitive Damages

Defendant asks the Court to strike Plaintiff's requests for both emotional distress and punitive damages. However, Defendant fails to invoke the appropriate legal standard governing such a motion. Specifically, a request to strike material from a pleading must be brought under Rule 12(f), not Rule 12(b)(6). Because Defendant relies solely on Rule 12(b)(6) as the legal standard in support of its motion, the request to strike is procedurally improper. Accordingly, the Court denies Defendant's request to strike Plaintiff's emotional distress and punitive damages.

## CONCLUSION

For these reasons, the Court denies Defendant's motion to dismiss [28]. The parties should file a joint status report at least 3 days prior to the 9/8/25 hearing per the Court's standing order.

**IT IS SO ORDERED.**

Date: 8/28/2025

Entered: _____
SHARON JOHNSON COLEMAN
United States District Judge